

T LDL-C CALIBRATOR

CALIBRATOR FOR LDL-C ASSAY

Introduction

T LDL-C Calibrator is intended to be used for the calibration of LDL-C assay.

Calibrator Storage, Stability & Handling Shelf - Life

Unopened calibrator is stable when stored at 2 - 8°C until the expiration date printed on the vial label.

Preparation of Calibrator & Stability

Lyophilized serum T LDL-C Calibrator should be reconstituted by adding 1.0 ml of distilled or deionized water. Close the vial and let stand for 20 minutes. Dissolve the contents of the vial by swirling gently to avoid the formation of foam. **Do not shake.** Reconstituted T LDL-C Calibrator is stable for **14 days at 2 - 8°C**. Reconstitution stability of the calibrator may be extended upto 28 days by aliquoting and freezing the reconstituted calibrator preparation at less than -80°C.

Calibrator Concentration

The calibrator concentration is printed on the vial label.

Indications of Deterioration

Presence of extreme turbidity or microbial growth may indicate deterioration.

Components

T LDL-C Calibrator is a preparation of lyophilized human serum containing lipoproteins from the various lipoprotein classes including low-density lipoproteins.

Calibration Procedure

The calibrator should be used to analyze patient samples in accordance with the instructions outlined in Accurex T LDL-C Reagent package insert.

The value of T LDL-C Calibrator is assigned by procedures traceable to the National Reference System for Cholesterol (NRS/CHOL). Calibration materials have concentrations around the medical decision level.

Refer to the instrument manufacturer's recommendation for calibration frequency.

Precautions & Warnings

1. For *in vitro* diagnostic use.
2. Do not pipette by mouth.
3. Human material used in the preparation of this product has been tested and found nonreactive for the presence of HBsAg, HCV and antibody to HIV 1/2. However, all human-based products should still be handled in accordance with good laboratory practices using appropriate precautions to avoid transmission of any infectious diseases.
4. Do not use the calibrator after the expiration date printed on the box.
5. Sodium azide at a concentration of 0.1% has been added to T LDL-C Calibrator as an antibacterial agent. Sodium azide may react with lead and copper plumbing to form potentially explosive metal azide buildup.

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|--|------------------------------|---|------------------------|
|  IVD | In Vitro Diagnostic Use |  | Date of Manufacturing |
|  | Consult Instructions for use |  | Use by (YYYY-MM-DD) |
|  | Catalogue Number |  | Temperature Limitation |
|  | Batch Code |  | Manufacturer |


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